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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,231	03/14/2006	Michael E. Stiles	C66010.1	9705
24286 7590 09/16/2008 WILLIAM J BUNDREN THE LAW OFFICE OF WILLIAM J BUNDREN 734 LaRue Road Millersville, MD 21108			EXAMINER BADR, HAMID R	
			ART UNIT 1794	PAPER NUMBER
			MAIL DATE 09/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,231

Applicant(s)

STILES ET AL.

Examiner

HAMID R. BADR

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Drawings

1. Fig. 1.1, 1.2 and 1.3 are objected to for not being legible. Either the title or X or Y axis labels are not legible. Correction is required.

Information Disclosure Statement

2. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, and 15 of copending Application No. 11/013,929. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two applications is that the present claims are broader with respect to the bacterial cultures. It would have been obvious to one of ordinary skill in the art that the specific disclosure of CB1, CB2 and CB3 would fall within the scope of the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claim 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9 of copending Application No. 10/870,032. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two applications is that the present claims are broader with respect to the bacterial cultures. It would have been obvious to one of ordinary skill in the art that the specific disclosure of CB1, CB2 and CB3 would fall within the scope of the present claims.

Claims 1-5 are directed to an invention not patentably distinct from claims 4-9 of commonly assigned 10/870,032. Specifically, although the conflicting claims are not identical, they are not patentably distinct for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/870,032, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon

the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

6. Claim 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 11/931,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two applications is that the present claims are broader with respect to the bacterial cultures. It would have been obvious to one of ordinary skill in the art that the specific disclosure of CB1, CB2 and CB3 would fall within the scope of the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-3, 5, 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must

be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1 and 5 are indefinite fro "*Listeria*". Since the exact species is not claimed, it is not clear what is meant by "*Listeria*". It is unclear what the applicants regard as the invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

12. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahn et al. (1990, Antibacterial activity of lactic acid bacteria isolated from vacuum packaged meats; hereinafter R1) .
13. R1 investigates the lactic acid bacteria isolated from vacuum-packaged fresh meat which are shown to produce antagonistic substances. The activity is not lost from supernatant fluids as a result of heat treatment. Inhibitory spectra of some stains included *Listeria monocytogenes*. There are more than one bacteriocin involved when looking at different strains (Abstract).
14. R1 discloses that the active supernatant fluid from each producer strain was treated with catalase, protease and heat inactivated protease. In all cases antagonism was eliminated by protease treatment but not by catalase or heat inactivated protease (page 306, col. 2, first paragraph).
15. R1 discloses that inoculation of 10^9 organisms /g was necessary to inhibit the development of the spoilage microflora (Page 309, col. 1, lines 2-3). It is clear that this level of inoculation exceeds the level of natural contamination as presently claimed.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahn et al. (1990, Antibacterial activity of lactic acid bacteria isolated from vacuum packaged meats; hereinafter R1) in view of Clayton et al. (US 2002/0009520; hereinafter R2).

18. R1 investigates the lactic acid bacteria isolated from vacuum-packaged fresh meat which are shown to produce antagonistic substances. The activity is not lost from supernatant fluids as a result of heat treatment. Inhibitory spectra of some stains included *Listeria monocytogenes*. There are more than one bacteriocin involved when looking at different strains (Abstract).

19. R1 discloses that the predominance of lactic acid bacteria in vacuum-packaged meats markedly extends their refrigerated storage (page 302, col. 2, first paragraph).

20. R1 discloses that the antagonistic activity was tested against *Listeria innocua*, and *Listeria monocytogenes*. (page 304, Col. 1, third paragraph). At 30C growth occurred without bacteriocin production, except for strains UAL11, and UAL89 (page 304, Col. 2, Results, first paragraph). R1 reports on several bacteriocin producing strains including UAL26 as presently claimed (page 305, Table 1). R1 discloses that UAL26 is most probably *Carnobacterium piscicola*. R1 discloses that the active supernatant fluid from each producer strain was treated with catalase, protease and heat inactivated protease. In all cases antagonism was eliminated by protease treatment but not by catalase or heat inactivated protease (page 306, col. 2, first paragraph). Given the antagonistic property of the supernatant, it is clear that those of

skill in the art can employ the bacteriocin, without the live cultures, to foods for the purpose of preservation. Therefore, the limitation of claim 3 is also obvious.

21. R1 discloses that the controlled growth of lactic acid bacteria in meats has only been exploited in fermented sausage meats (page 308, col. 2, lines 1-4). R1 discloses that lactic acid bacteria isolated from meats should be able to grow and dominate the meat microflora (page 309, first paragraph).

22. R1 discloses that inoculation of 10^9 organisms /g was necessary to inhibit the development of the spoilage microflora (Page 309, col. 1, lines 2-3). It is clear that this level of inoculation exceeds the level of natural contamination as presently claimed.

23. While R1 gives the details of bacteriocin producing strains and their role in extending the shelf life of foodstuffs, it is generally silent regarding the methods of application of such strains to foodstuffs.

24. R2 discloses a method for preserving a food product such as meat, comprising the steps of inoculating meat with an effective amount of non-pathogenic bacteria in order to inhibit the growth of undesired pathogenic bacteria. (Abstract).

25. R2 teaches using a group of lactic acid bacteria such as *L. lactis* for preservation of foods [0026]. R2 teaches of inoculating a food product with bacteria able to proliferate from 1C to 35C [0027]. R2 discloses inoculating the surface of a food product with beneficial bacteria [0029].

26. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to try bacteriocin producing strains as taught by R1 adopting the methods of R2 for the preservation of meat by either using the organisms or the culture

supernatant containing bacteriocins. One would do so to benefit of biological preservation of foods. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be reasonable expectation of success in applying such strains for the preservation of foodstuffs.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794